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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,710	11/04/2003	Vinod Sharma	P-10314.00	7091
27581	7590	06/13/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			EVANISKO, GEORGE ROBERT	
			ART UNIT	PAPER NUMBER
			3762	
DATE MAILED: 06/13/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/701,710

Applicant(s)

SHARMA ET AL.

Examiner

George R. Evanisko

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 23-34 is/are rejected.
- 7) ☒ Claim(s) 20-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 and 23-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, “engaged along a target site” is vague since it sounds as if there is a connection to the body. Apparatus claims can not claim connection to the body. It is suggested to use “and adapted to engage a target site”. In line 4, “to deliver a voltage sensitive dye” is vague and inferentially including the dye since the dye has not been positively recited but the delivery member is claiming a positive connection to it (“to deliver...dye”). It is unclear if the applicant is positively claiming the dye or functionally claiming the dye. In line 7, “to transmit a signal” is vague since nothing has been set forth to cause a signal to be produced. It is suggested to use “adapted to transmit...”.

In claims 3, 4, 6, the claims are vague and are not further limiting the independent claim since the target site or tissue has not been positively recited. It is suggested to state that the body is adapted for these certain tissues.

In claim 7, the claim is vague and incomplete since the electrodes are not connected to any other elements. In addition, “to deliver therapy” is inferentially including the therapy.

In claim 10, the claim is incomplete for omitting a connection of the fixation member to another element.

In claim 17, “a glucocorticosteriod” is inferentially included.

In claim 18, “and inhibiting pacing output” is vague since the device has not been set forth to have any pacing output.

In claim 23, “the pacing pulse” lacks antecedent basis.

In claim 25, “in response to an arrhythmia being detected” is vague and unclear if this step is being claimed. Method steps should be in the active voice. It is suggested to state “detecting an arrhythmia and wherein said voltage...”.

In claim 27, “along the target site” is vague. In the next to last line “the action potential” should be “an action potential”.

Claims 30 and 33 are vague since the claims have not set forth what element is performing the functions in the claims (such as detecting loss of capture or arrhythmia). In addition, claim 33 is vague since it depends from a system claim but uses the language “the method further comprises”.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 4, 6, 7, 8, 9, 17, 19, and 27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bassen et al (5678550).

Bassen discloses the use of an elongated body, 5, with the claimed delivery member as inner surface of 5 and/or outer surface of endoscope 10, with a transmission member, 13, and control circuitry 60/61, that detects the electrical activity of the cardiac tissue. This electrical activity is the generated action potential. For claim 7, figure 3 shows the use of additional electrodes to deliver therapy and is capable of meeting the functional use recitations of the action potential since the electrodes can deliver any electrical therapy. For claim 9, Bassen's transmission member is capable of meeting the functional use recitations of being extendable between the two positions since the endoscope with transmission member can be moved between those positions

In the alternative, Bassen discloses the claimed invention except for the separate delivery member, the control circuitry for determining whether an action potential is detected, and for

Art Unit: 3762

claim 17, another delivery member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus and method for detecting cardiac activity as taught by Bassen, with a separate delivery member, control circuitry for determining whether an action potential is detected, and another delivery member since it was known in the art that in situ catheters use a separate delivery member and another delivery member to provide multiple pathways to easily deliver drugs and fluids to target tissue without the problem of mixing of the fluids and to allow selective control of each fluid and since it was known in the art to have control circuitry to determine whether an action potential is detected to determine whether the tissue is being properly stimulated or whether there is an abnormal rhythm.

Claims 2, 10, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bassen.

Bassen discloses the claimed invention except for the delivery member being inside the elongated body then advanced out of the distal end (claim 2), the delivery member being a needle (claim 15), and a fixation member on the elongated body distal end (claim 16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter system and method as taught by Bassen, with the delivery member being inside the elongated body then advanced out of the distal end (claim 2), the delivery member being a needle (claim 15), and a fixation member on the elongated body distal end (claim 16) since it was known in the art that catheter systems and methods use: the delivery member being inside the elongated body then advanced out of the distal end, such as the delivery member being a needle to allow the catheter to be introduced into the body without causing damage from the

delivery member, and the delivery member advanced outside the catheter to directly apply the dye/fluid to the proper place in the body; and a fixation member on the elongated body distal end to allow the elongated member to be stationed at the correct position in the body the entire time the catheter is used for the therapy and/or diagnosis.

Allowable Subject Matter

Claims 5, 11-14, 24-26, and 28-34 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 20-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schnitzer and Gray are two teachings of many showing the use of determining the action potentials. Lee is one example of many showing the use of extendable delivery members, such as needles.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762

6/2/6

GRE
June 2, 2006